

INTERNATIONAL COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

10/526256
REC'D 17 SEP 2004
WIPO PCT

Rec'd PCTO 28 FEB 2005

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|--|---|---|--|
| Applicant's or agent's file reference 66783-138 | | FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416) | |
| International application No. PCT/US03/23926 | International filing date (day/month/year) 30 July 2003 (30.07.2003) | Priority date (day/month/year) 30 August 2002 (30.08.2002) | |
| International Patent Classification (IPC) or national classification and IPC IPC(7): C07H 21/04; C12Q 1/68 and US Cl.: 435/6; 536/23.1 | | | |
| Applicant CEDARS-SINAI MEDICAL CENTER | | | |
| <p>1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of <u>3</u> sheets, including this cover sheet.</p> <p><input type="checkbox"/> This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).</p> <p>These annexes consist of a total of <u> </u> sheets.</p> | | | |
| <p>3. This report contains indications relating to the following items:</p> <p>I <input checked="" type="checkbox"/> Basis of the report</p> <p>II <input type="checkbox"/> Priority</p> <p>III <input type="checkbox"/> Non-establishment of report with regard to novelty, inventive step and industrial applicability</p> <p>IV <input type="checkbox"/> Lack of unity of invention</p> <p>V <input checked="" type="checkbox"/> Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p>VI <input type="checkbox"/> Certain documents cited</p> <p>VII <input type="checkbox"/> Certain defects in the international application</p> <p>VIII <input type="checkbox"/> Certain observations on the international application</p> | | | |
| Date of submission of the demand 17 March 2004 (17.03.2004) | | Date of completion of this report 19 August 2004 (19.08.2004) | |
| Name and mailing address of the IPEA/US Mail Stop PCT, Attn: IPEA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703) 305-3230 | | Authorized officer Jeanine Enewold Goldberg Telephone No. (703) 308-0196 <i>Janice Ford for</i> | |

Form PCT/IPEA/409 (cover sheet)(July 1998)

I. Basis of the report**1. With regard to the elements of the international application:***

- ☐ the international application as originally filed.
- ☒ the description:
pages 1-63 _____ as originally filed
pages NONE _____, filed with the demand
pages NONE _____, filed with the letter of _____.
- ☒ the claims:
pages 64-67 _____, as originally filed
pages NONE _____, as amended (together with any statement) under Article 19
pages NONE _____, filed with the demand
pages NONE _____, filed with the letter of _____.
- ☒ the drawings:
pages 1-15 _____, as originally filed
pages NONE _____, filed with the demand
pages NONE _____, filed with the letter of _____.
- ☒ the sequence listing part of the description:
pages 1-19 _____, as originally filed
pages NONE _____, filed with the demand
pages NONE _____, filed with the letter of _____.

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language _____ which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☒ contained in the international application in printed form.
- ☒ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages NONE
- ☐ the claims, Nos. NONE
- ☐ the drawings, sheets/fig NONE

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

** Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**1. STATEMENT**

| | | |
|-------------------------------|--------------------|-----|
| Novelty (N) | Claims <u>NONE</u> | YES |
| | Claims <u>1-23</u> | NO |
| Inventive Step (IS) | Claims <u>NONE</u> | YES |
| | Claims <u>1-23</u> | NO |
| Industrial Applicability (IA) | Claims <u>1-23</u> | YES |
| | Claims <u>NONE</u> | NO |

2. CITATIONS AND EXPLANATIONS

Claims 1-23 lack novelty under PCT Article 33(2) as being anticipated by Abreu et al (Gastroenterology, Vol 122, No. 4, Suppl, April 2002, A29-246).

Abreu teaches mutations in NOD2 are associated with fibrostenosing disease in patients with Crohn's disease. Genotyping was performed on the rare alleles of NOD2 gene including R675W, G881R and 980fs. The univariate analysis revealed that the CD-associated NOD2 variants are significantly associated with fibrostenosing disease in two panels for the three variants combined. Additionally, Abreu teaches that 980fs demonstrated the greatest association with fibrostenosing disease. These three mutations appear to correspond to the mutations taught in the instant Table 6.

Claims 1-23 meet the criteria set out in PCT Article 33(4), and thus meet industrial applicability because the subject matter claimed can be made or used in industry.

----- NEW CITATIONS -----

PATENT COOPERATION TREATY

PCT

NOTE OF INFORMAL COMMUNICATION WITH THE APPLICANT

(PCT Rule 66.6)

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| International application No. PCT/US03/23926 | Applicant's or agent's file reference 66783-138 | Date of informal communication (day/month/year) 09 September 2004 |
| Applicant CEDARS-SINAI MEDICAL CENTER | | |

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|---|---|--|--|--|---|--|--|--|--|--|--|--|--|--|--|--|--|
| <u>Communication</u> <input checked="" type="checkbox"/> by telephone <input type="checkbox"/> personal | <table style="width: 100%;"> <tr> <td style="width: 40%;"><u>Participants</u></td> <td style="width: 20%;"><input checked="" type="checkbox"/> Identity checked</td> <td style="width: 20%;"><input type="checkbox"/> authorization checked</td> <td style="width: 20%;"><input type="checkbox"/> personally known</td> </tr> <tr> <td><input type="checkbox"/> Applicant: CE/DAR,S-SINAI MEDICAL CENTER</td> <td colspan="3"></td> </tr> <tr> <td><input checked="" type="checkbox"/> Agent: Andrea Gashler</td> <td colspan="3"></td> </tr> <tr> <td><input checked="" type="checkbox"/> Examiner(s): Jeanine Goldberg</td> <td colspan="3"></td> </tr> </table> | <u>Participants</u> | <input checked="" type="checkbox"/> Identity checked | <input type="checkbox"/> authorization checked | <input type="checkbox"/> personally known | <input type="checkbox"/> Applicant: CE/DAR,S-SINAI MEDICAL CENTER | | | | <input checked="" type="checkbox"/> Agent: Andrea Gashler | | | | <input checked="" type="checkbox"/> Examiner(s): Jeanine Goldberg | | | |
| <u>Participants</u> | <input checked="" type="checkbox"/> Identity checked | <input type="checkbox"/> authorization checked | <input type="checkbox"/> personally known | | | | | | | | | | | | | | |
| <input type="checkbox"/> Applicant: CE/DAR,S-SINAI MEDICAL CENTER | | | | | | | | | | | | | | | | | |
| <input checked="" type="checkbox"/> Agent: Andrea Gashler | | | | | | | | | | | | | | | | | |
| <input checked="" type="checkbox"/> Examiner(s): Jeanine Goldberg | | | | | | | | | | | | | | | | | |

Summary of communication:

The examiner called applicant to determine whether it would be acceptable to prepare the IPER (409) for this application. Applicant indicated that would be acceptable.

☐ An extension of time limit is granted (Form PCT/IPEA/427).

☒ A copy of this note is being sent to the applicant with Form PCT/IPEA/429.

PCT/IPEA/424.

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| Name and mailing address of the IPEA/US Mail Stop PCT, Attn: IPEA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703) 305-3230 | Authorized officer Jeanine Enewold Goldberg Telephone No. (703) 308-0196 <div style="text-align: right; font-family: cursive; font-size: 1.2em;"> <i>Jeanine Ford</i> <i>for</i> </div> |
|---|---|

Form PCT/IPEA/428 (July 1992)